

Section 4 510(k) Summary

OCT 23 2007

4.0 Summary Information

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:	Abbott Vascular
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Contact Person:	George J. Prendergast, Senior Regulatory Affairs Associate
Date Prepared:	October 1, 2007
Device Trade Name:	Fox™ sv PTA Catheter
Device Common Name:	PTA Catheter
Device Classification:	Class II
Device Classification Number:	21 CFR 870.1250
Device Product Code:	LIT

4.1 Predicate Devices

The modified Fox™ sv PTA Catheter is substantially equivalent to the Fox sv PTA Catheter (K062843) cleared 10/17/2006 and the Cordis® SAVVY® PTA Dilatation Catheter (K942094) cleared 11/1/1994. The change made to the Fox sv PTA Catheter focuses on the catheter.

4.2 Device Description

The Fox sv PTA Catheter is a standard over-the-wire PTA catheter. The double lumen catheter has a balloon located near the distal tip. One lumen is used for inflation of the balloon, while the second lumen allows access to the distal tip of the catheter for guidewire insertion (maximum 0.018"). The balloon material expands to a known diameter at specific pressures.

4.3 Intended Use

The intended use for the device has not changed as a result of the modification.

The Fox sv PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries and native or synthetic

arteriovenous dialysis fistulae. This catheter is not intended for the expansion or delivery of stents.

4.4 Summary of Technological Characteristics Compared to Predicate Devices

The Fox™ sv PTA Catheter subject device is identical in technological characteristics, with the exception of the catheter length, to the Fox sv PTA Catheter predicate device. The subject device catheter has been extended to 150cm from 135cm. The subject device is substantially equivalent to the Cordis® SAVVY® PTA Catheter with respect to product code, classification section, classification name, intended use, contraindications, catheter length, balloon diameters and lengths, introducer sheath size, and guidewire compatibility.

4.5 Summary of Substantial Equivalence

The Fox sv PTA Catheter subject device is substantially equivalent to the predicate devices. The results of the *in vitro* bench tests and analyses and biocompatibility testing demonstrate the safety and effectiveness of the Fox sv PTA Catheter subject device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 23 2007

Abbott Vascular, Inc.
c/o Mr. George Prendergast
Senior Regulatory Affairs Associate
3200 Lakeside Drive
Santa Clara, CA 95054

Re: K072824

Trade/Device Name: Fox sv PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: October 1, 2007
Received: October 2, 2007

Dear Mr. Prendergast:


We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director

Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 7 Indications for Use

510(k) Number (if known) K072824

Device Name Fox™sv PTA Catheter


Indications for Use The Fox sv PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal and profunda arteries and native or synthetic arteriovenous dialysis fistulae.

This catheter is not intended for the expansion or delivery of stents.

Prescription Use X AND/OR Over-the-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K072824